ST. JUDE MEDICAL
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July 17, 2008

Via Electronic Filing

Marlene H. Dortch, Secretary
Federal Communications Commission
445 12th Street SW
Washington, DC 20554

Re: Written *Ex Parte*: *Investigation of the Spectrum Requirements for Advanced Medical Technologies* – ET Docket No. 06-135; *Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communications Service at 401-402 and 405-406 MHz* – RM-11271

Dear Ms. Dortch:

On July 18, 2006, the Commission released a Notice of Proposed Rulemaking ("*Notice*") in the above-captioned proceeding, which explored expanded use of implantable and body-worn devices in the existing Medical Implant Communications Service ("MICS") core band at 402-405 MHz, as well as in the proposed new MedRadio "wing" bands at 401-402 MHz and 405-406 MHz.[1] In its comments in response to the *Notice*, St. Jude Medical stated that the core MICS band should be assigned only to applications that permit the "downloading of therapeutic data to active implantable medical devices . . . and not to general communication with, for example, body worn devices."[2]

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1 *Investigation of the Spectrum Requirements for Advanced Medical Technologies, Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communications Service at 401-402 and 405-406 MHz, DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules*, Notice of Proposed Rulemaking, Notice of Inquiry, and Order, 21 FCC Rcd 8164 (2006).

2 Letter from Kathleen M. Chester, St. Jude Medical, to Marlene H. Dortch, FCC, RM-11271 (Oct. 27, 2006).

St. Jude Medical wishes to clarify that it believes that the Commission's MedRadio rules should permit certain medical devices that have been partially implanted in the human body to operate at 402-405 MHz. In particular, the Commission should permit body-worn transmitters connected percutaneously to an implanted device to operate at 402-405 MHz under the same rules as implanted transmitters, if the following conditions are met: (i) there is a sound diagnostic or therapeutic justification for operating the transmitter as a body-worn device; (ii) the body-worn transmitter is intended to be replaced by a fully-implanted permanent transmitter after a brief period of time (for example, no more than 30 days); (iii) the body-worn transmitter is "listen before talk" and "frequency agile"; (iv) the body-worn transmitter operates at an appropriate measured field strength limit to account for the lack of body absorption of radiated power that occurs with implanted transmitters; (v) the body-worn transmitter otherwise complies with FCC requirements applicable to implanted transmitters; and (vi) the fully implanted transmitter will meet all applicable FCC requirements.

Permitting partially implanted devices meeting these requirements to operate at 402-405 MHz would benefit patients by enhancing their medical care and expanding their diagnostic and therapeutic options. For example, doctors would be able to test some medical implants during an evaluation period in which the transmitter is body worn; only after the evaluation period has demonstrated the efficacy of the device would a patient undergo the invasive procedure of having the permanent transmitter implanted in his or her body. In this manner, doctors will be able to identify those patients for whom full implantation is appropriate, while minimizing the healthcare costs and risks for patients who are not suitable candidates for a particular medical device.

Permitting operation of such partially implanted devices would pose little, if any, risk of harmful interference at 402-405 MHz. As noted, the body-worn transmitters would operate only for limited periods of time and would be subject to appropriate field strength limits. By contrast, relegating such transmitters to spectrum outside of 402-405 MHz would likely subject them to unacceptable interference or other operational difficulties, thereby impairing the usefulness of the evaluation period. Moreover, doctors would not be able to evaluate the efficacy of such transmitters because they would be operating on frequencies other than those on which the implanted transmitter would ultimately operate. As a result, doctors (and patients) would lack confidence that the device's performance during the evaluation period would accurately predict performance after implantation of the transmitter.

For the foregoing reasons, the public interest would be served by permitting appropriate medical devices to operate on a partially-implanted basis at 402-405 MHz. St. Jude Medical therefore urges the Commission to adopt MedRadio rules that unambiguously permit such operation.

Pursuant to the Commission's rules, this letter is being submitted for inclusion in the public record of the above-referenced proceedings.

Sincerely,

Kathleen M. Chester

Kathleen M. Chester
Vice President, Regulatory Affairs
St. Jude Medical Cardiac Rhythm Management Division

cc: Ira Keltz
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